



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94102-7070  
Telephone: 510-337-6700

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

April 29, 1998

Our Reference No.: 29-40069

Kazu Hayashida, Director  
State Department of Transportation  
869 Punchbowl Street  
Honolulu, Hawaii 96813

**WARNING LETTER**

Dear Mr. Hayashida:

On April 8, 1998 FDA Investigator Randall P. Zielinski conducted an inspection of the watering points located on Piers 1, 2, and 3 at the Port of Hilo in Hilo, Hawaii. Your operations at this site are in serious violation of the federal regulations for interstate conveyance sanitation, Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act. Observations made by FDA Investigator Zielinski were listed on the FDA 483, Inspectional Observations, and discussed with Mr. John Moses, Acting Harbor Master, at the conclusion of the inspection.

Lack of adequate protection for the drinking water supply at the port was evidenced by the lack of backflow prevention devices on the potable water hydrants located on the piers, and the lack of caps to protect the hydrants from environmental contamination. On Pier 3, live adult cockroaches were observed in three of five potable water hydrant pits.

These conditions are likely to result in contamination of drinking water and could lead to a serious disease outbreak on vessels serviced at the port.

The findings were discussed with Mr. John Moses at the conclusion of the inspection, and a copy of the FDA 483, Inspectional Observations, was provided to him. A copy of the FDA 483 is being provided to you for your information.

Based on these findings, your facility has been classified "Provisional". A Provisional classification means that if the deficiencies are not corrected within thirty (30) working days from the receipt of this notification, your facility will be placed on "Not Approved" status.

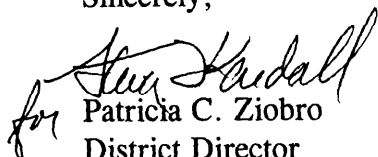
A "Not Approved" status means that potable water will be prohibited from use by interstate conveyances at the Port of Hilo.

Failure to take prompt corrective action may result in appropriate regulatory action, such as injunction, without further notice. You should notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the violations. If corrective action cannot be completed within thirty (30) working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent to:

Randall P. Zielinski, CSO/ITS  
U.S. Food and Drug Administration  
1431 Harbor Bay Parkway  
Alameda, CA 94502

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

  
for Patricia C. Ziobro  
District Director  
San Francisco District

Enclosure: FDA 483

cc: Mr. John Moses, Acting Harbor Master  
State Department of Transportation, Harbors Division  
Port of Hilo  
Hilo, HI 96720

Mr. James Nobles, Executive Vice President  
American Hawaii Cruises  
2100 North Nimitz Hwy.  
Honolulu, HI 96819